3404 Cooney Drive, Helena, MT 59602 Phone 406.443.6002 • Toll Free Phone 1.800.395.7961 Fax 406.513.1928 • Toll Free Fax 1.800.294.1350

Montana Medicaid Prior Authorization Request Form for Use of Victrelis® (boceprevir)

Victrelis[®] Initial Approval Form

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Today's Date:	Anticipated Victrelis Start Date:

I. Patient Readiness Evaluation:

Patient psychosocial readiness is a critical component for Hepatitis C treatment success. It is important that any potential impediments to the effectiveness of treatment have been identified and that a plan for dealing with these impediments has been developed. The patient must be educated that abuse of alcohol may cause further liver damage and that abuse of IV injectable drugs will increase the risk of re-infection of Hepatitis C if the virus is cleared. Given the high cost of Hepatitis C treatment, we want to ensure that both the provider and the patient feel that the patient is committed to effectively start and successfully adhere to treatment. We highly recommend that you use a patient readiness evaluation tool such as Prep-C, a free interactive online tool which can be found at the following website: https://prepc.org/. Please discuss the following questions with your patient, document their responses below, and have patient sign page 2:

- 1. Does patient have a history of alcohol abuse? Yes No
 - If yes, how long has it been since patient last used alcohol?
 - If yes, is patient attending a support group or receiving counseling? Yes No
- 2. <u>Does patient have a history of injectable drug abuse?</u> Yes No
 - If yes, how long has it been since patient last used an injectable drug?
 - If yes, is patient attending a support group or receiving counseling? Yes No
- 3. Does patient have a history of any other controlled-substance abuse? Yes No
 - If yes, how long has it been since patient last used this substance?
 - If yes, is patient attending a support group or receiving counseling? Yes No
- 4. Does patient have difficulties with medication compliance and/or showing up for appointments? Yes No
 - If yes, how will compliance/involvement be improved?
- 5. Does patient have mental health conditions that are not being adequately treated? Yes No
 - If yes, please explain, and state the plan for treatment:
- 6. <u>Does patient have adequate social support</u>? Yes No
 - If not, please state a plan to improve support:

MT Medicaid Hepatitis C Patient Readiness Criteria:

Patient signature:

- 1. Patient must <u>not</u> have a history of alcohol abuse, injectable drug abuse, and/or other controlled-substance abuse for at least <u>6 months</u> prior to starting Hepatitis C treatment. Patient involvement in a support group or counseling is highly encouraged for successful abstinence.
- 2. Patient must be reasonably compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment.
- 3. Patient must have a history of showing up for scheduled appointments/labs leading up to the prescribing of Hepatitis C treatment.
- 4. If patient has mental health conditions, patient must be compliant with mental health medications and/or psychotherapy. If patient has mental health conditions that are not currently being treated, then a mental health consult to assess for patient readiness will be required before Hepatitis C treatment can begin.

II.	MT Medicaid V	ictrelis [®] Requi	rements:					
Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive tests: APRI score, FibroSure score, or FibroScan results]								
——Patio	ent's Hepatitis C H	istory: (Please circl	e all that apply)					
	Liver status:	non-cirrhotic	compensated cirrhosis					
2.	Previous medication hx:	treatment naïve	null responder	partial responder	relapse			
List a	any previously tried H	epatitis C treatment	s and response:					

Date:

Patient must meet <u>ALL</u> of the following criteria: (Please check all that apply)

- O Patient Readiness Evaluation (page 1) must be completed and patient must meet all of the Patient Readiness Criteria listed on page 2
- O Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive test results: APRI score, FibroSure score, or FibroScan results]
- O All chart notes related to Hepatitis C evaluation/treatment must be included
- O Diagnosis of chronic Hepatitis C, genotype 1
- O Never had previous treatment with Victrelis[®] or other HCV NS3/4A protease inhibitors [ex: Incivek[®] (telaprevir) or Olysio[®] (simeprevir)]
- O Patient must be over the age of 18 years
- O Must receive concomitant peg-interferon and ribavirin
- O Has completed (or will have completed at time of initiation) 4 weeks of peg-interferon and ribavirin
- O Must be prescribed by (or had a documented consult with) a gastroenterologist, infectious disease specialist, or a practitioner specializing in the treatment of hepatitis. Attach consult notes.
- O Patient must not have HIV or Hepatitis B co-infection
- O Must not have decompensated cirrhosis
- O Patient must not have a history of solid organ transplant
- O Female patient or male patient's female partner must not be pregnant or planning to become pregnant during treatment or within 6 months after stopping treatment.
- O Patient must not be taking any of the following medications that are contraindicated with Victrelis[®]. **Please circle medication name if patient is taking any of the following:**
 - alfuzosin, carbamezapine, phenobarbital, and phenytoin, rifampin, dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, St. John's Wort, lovastatin, simvastatin, drosperinone, sildenafil or tadalafil for treatment of pulmonary arterial hypertension, pimozide, triazolam, or orally administered midazolam

Limitations:

- 1. Initial approval will be granted for **12 weeks** of Victrelis[®] (through treatment week 16).
- 2. Dosing will be limited to **12 capsules per day** (336 capsules/28 days).
- 3. Continuation will require documentation of HCV RNA viral load at baseline, 4, 8, 12, & 24 weeks in therapy.

Please complete form, attach documentation, and fax to: Medicaid Drug Prior Authorization Unit at 1-800-294-1350 3404 Cooney Drive, Helena, MT 59602 Phone 406.443.6002 • Toll Free Phone 1.800.395.7961 Fax 406.513.1928 • Toll Free Fax 1.800.294.1350

Montana Medicaid Prior Authorization Request Form for Use of Victrelis® (boceprevir)

Victrelis® Renewal Form

Patient's Name:		Patient's Medicaid ID#:				
Patient's DOB:		Patient's Gender:				
Provider's Na	me:	Provider's Specialty:				
Provider's Phone #:		Provider's Fax #:				
Date:						
Data nog inte	outovan and vibavivin was started.					
Date peg-mie	erferon and ribavirin was started:					
Date Victrelia	s® was started:					
Current Treatment Week:						
D 1D	•					
Renewal Re	equirements: All of the following requi	irements must be met: (Please check all	that apply)			
0	Peg-interferon alfa and/or ribavirin must not	have been discontinued				
	O Patient must have been compliant with peg-interferon alfa, ribavirin, and Victrelis® therapy as per protocol					
0	O HCV RNA levels must be documented at the appropriate times below (as soon as available):					
	□ HCV RNA level at Baselin e	e (before starting peg-interferon +	ribavirin)			
		Result (IU/ml):				
	☐ HCV RNA level at Treatm	ent Week 4 (at start of Victrelis®	therapy)			
	Date of test:	Result (IU/ml):	$_{\perp}$ \square Undetectable			
	☐ HCV RNA level at Treatment Week 8 (after 4 weeks of Victrelis [®])					
	Date of test:	Result (IU/ml):	$_$ \square Undetectable			
	☐ HCV RNA level at Treatment Week 12 (after 8 weeks of Victrelis®)					
		Result (IU/ml):	,			
☐ HCV RNA level at Treatment Week 24 (after 20 weeks of Victrelis [®])						
		•	· · · · · · · · · · · · · · · · · · ·			
	Date of test.	Result (IU/ml):				

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Renewal Limitations:

- 1. After treatment week 16:
 - If week 12 HCV RNA is >100 IU/ml, then further authorization of Victrelis® will be denied.
 - If week 12 HCV RNA is <100 IU/ml, then Victrelis® will be authorized for 12 weeks (through treatment week 28).

2. After treatment week 28:

- A. Non-cirrhotic patients:
 - Treatment-naive:
 - o If week 24 HCV-RNA is detectable, then further authorization of Victrelis® will be denied.
 - o If week 8 and week 24 HCV-RNA are undetectable, then Victrelis® therapy is complete.
 - o If week 8 HCV-RNA is detectable, but week 24 HCV-RNA is undetectable, then Victrelis® will be authorized for 8 weeks (through treatment week 36).
 - Previous relapsers or partial responders:
 - o If week 24 HCV-RNA is detectable, then further authorization of Victrelis® will be denied.
 - o If week 24 HCV-RNA is undetectable, then Victrelis® will be authorized for 8 weeks (through treatment week 36).
- B. For patients with compensated cirrhosis, patients who were null responders with previous therapy of peg-interferon alfa and ribavirin, or treatment-naïve patients who are poorly interferon responsive at treatment week 4:
 - If week 24 HCV-RNA is detectable, then further authorization of Victrelis® will be denied.
 - If week 24 HCV-RNA is undetectable, then Victrelis® therapy will be authorized for 20 weeks (through treatment week 48).